

B<sup>2</sup> 1042. The modified release tablet of claim 33 wherein the  $C_{max}$ ,  $AUC_{inf}$  and  $AUC_{0-12}$  are approximately proportional to dosage strength.

1143. The modified release tablet of claim 33 or 39 wherein the ratio of said first quantity of guaifenesin to said second quantity of guaifenesin is about 1:1 to about 1:5.

1244. The modified release tablet of claim 33 or 39 wherein the ratio of said first quantity of guaifenesin to said quantity of second quantity of guaifenesin is about 1:5.

B<sup>3</sup> 1446. The modified release tablet of claim 41 wherein the  $C_{max}$  of said tablet is at least 1900  $\mu\text{g/mL}$  and said tablet has an  $AUC_{inf}$  of at least 7000  $\text{hr} \cdot \mu\text{g/mL}$ .

B<sup>4</sup> 1648. The modified release tablet of claim 40 wherein the  $C_{max}$  of said tablet is at least 1000  $\mu\text{g/mL}$  and said tablet has an  $AUC_{inf}$  of at least 3500  $\text{hr} \cdot \mu\text{g/mL}$ .

[ Please add the following new claims 56-88 as follows:

B<sup>5</sup> 2456. A modified release product having two portions, wherein a first portion comprises a first quantity of guaifenesin in an immediate release form which becomes fully bioavailable in the subject's stomach and a second portion comprises a second quantity of guaifenesin in a sustained release form wherein the ratio of said first quantity to said second quantity provides a  $C_{max}$  in a human subject equivalent to the  $C_{max}$  obtained when the first of three doses of a standard immediate release formulation having one third the amount of guaifenesin is dosed every four hours over a 12 hour period and wherein said product also provides therapeutically effective bioavailability for at least twelve hours after a single dose in a human subject according to serum analysis.

2557. The modified release product of claim 56 wherein the total quantity of guaifenesin is from about 600 mg to about 1200 mg.

2658. The modified release product of claim 56 wherein the total quantity of guaifenesin is 600 mg.

2759. The modified release product of claim 56 wherein the total quantity of guaifenesin is 1200 mg.

2860. The modified release product of claim 56 wherein the  $C_{max}$ ,  $AUC_{inf}$  and  $AUC_{0-12}$  are approximately proportional to dosage strength.

2961. The modified release product of claim 56 or 57 wherein the ratio of said first quantity of guaifenesin to said quantity of second quantity of guaifenesin is about 1:1 to about 1:5.

<sup>30</sup><sub>62</sub> The modified release product of claim <sup>29</sup><sub>61</sub> wherein the ratio of said first quantity of guaifenesin to said quantity of second quantity of guaifenesin is about 1:5.

<sup>36</sup><sub>63</sub> The modified release product of claim <sup>27</sup><sub>59</sub> wherein the  $C_{max}$  of said product is from about 1600 to 2500  $\mu\text{g/mL}$  and said product has an  $AUC_{inf}$  of from about 5600 to 8750  $\text{hr} \cdot \mu\text{g/mL}$ .

<sup>32</sup><sub>64</sub> The modified release product of claim <sup>27</sup><sub>59</sub> wherein the  $C_{max}$  of said product is at least 1900  $\mu\text{g/mL}$  and said product has an  $AUC_{inf}$  of at least 7000  $\text{hr} \cdot \mu\text{g/mL}$ .

<sup>33</sup><sub>65</sub> The modified release product of claim <sup>26</sup><sub>58</sub> wherein the  $C_{max}$  of said product is from about 800 to 1250  $\mu\text{g/mL}$  and said product has an  $AUC_{inf}$  of from about 2800 to 4375  $\text{hr} \cdot \mu\text{g/mL}$ .

<sup>34</sup><sub>66</sub> The modified release product of claim <sup>26</sup><sub>58</sub> wherein the  $C_{max}$  of said product is at least 1000  $\mu\text{g/mL}$  and said product has an  $AUC_{inf}$  of at least 3500  $\text{hr} \cdot \mu\text{g/mL}$ .

<sup>35</sup><sub>67</sub> The modified release product of claim <sup>24</sup><sub>56</sub> wherein said product has a half life, according to serum analysis, of at least three hours.

<sup>36</sup><sub>68</sub> The modified release product of claim <sup>24</sup><sub>56</sub> wherein said first and second portions each comprise abutting substantially planar layers which form a bilayer tablet.

<sup>37</sup><sub>69</sub> The modified release product of claim <sup>24</sup><sub>56</sub> wherein said first portion is provided as a coating on said second portion.

<sup>38</sup><sub>70</sub> The modified release product of claim <sup>24</sup><sub>56</sub> which is a capsule containing said first and second portions.

<sup>39</sup><sub>71</sub> The modified release product of claim <sup>24</sup><sub>56</sub> which is approximately equally effective when administered to a patient on an empty or full stomach.

<sup>40</sup><sub>72</sub> The modified release product of claim <sup>27</sup><sub>59</sub> which has the serum guaifenesin concentration profile of Figure 10.

<sup>41</sup><sub>73</sub> A modified release product having two portions, wherein a first portion comprises a first quantity of guaifenesin in an immediate release form which becomes fully bioavailable in the subject's stomach and a second portion comprises a second quantity of guaifenesin in a sustained release form wherein the ratio of said first quantity to said second quantity is from about 1:1 to about 1:5 and the product provides a  $C_{max}$  in a human subject equivalent to the  $C_{max}$  obtained when the first of three doses of a standard immediate release formulation having one third the amount of guaifenesin is dosed every four hours over a 12 hour period and wherein said product also provides therapeutically effective bioavailability for at least twelve hours after a single dose in a human subject according to serum analysis.

42. The modified release product of claim 73 wherein the total quantity of guaifenesin is from about 600 mg to about 1200 mg.
43. The modified release product of claim 73 wherein the total quantity of guaifenesin is 600 mg.
44. The modified release product of claim 73 wherein the total quantity of guaifenesin is 1200 mg.
45. The modified release product of claim 73 wherein the  $C_{max}$ ,  $AUC_{inf}$  and  $AUC_{0-12}$  are approximately proportional to dosage strength.
46. The modified release product of claim 73 wherein the ratio of said first quantity of guaifenesin to said quantity of second quantity of guaifenesin is about 1:5.
47. The modified release product of claim 73 wherein the  $C_{max}$  of said product is from about 1600 to 2500  $\mu\text{g/mL}$  and said product has an  $AUC_{inf}$  of from about 5600 to 8750  $\text{hr} \cdot \mu\text{g/mL}$ .
48. The modified release product of claim 73 wherein the  $C_{max}$  of said product is at least 1900  $\mu\text{g/mL}$  and said product has an  $AUC_{inf}$  of at least 7000  $\text{hr} \cdot \mu\text{g/mL}$ .
49. The modified release product of claim 73 wherein the  $C_{max}$  of said product is from about 800 to 1250  $\mu\text{g/mL}$  and said product has an  $AUC_{inf}$  of from about 2800 to 4375  $\text{hr} \cdot \mu\text{g/mL}$ .
50. The modified release product of claim 73 wherein the  $C_{max}$  of said product is at least 1000  $\mu\text{g/mL}$  and said product has an  $AUC_{inf}$  of at least 3500  $\text{hr} \cdot \mu\text{g/mL}$ .
51. The modified release product of claim 73 wherein said product has a half life, according to serum analysis, of at least three hours.
52. The modified release product of claim 73 wherein said first and second portions each comprise abutting substantially planar layers which form a bilayer tablet.
53. The modified release product of claim 73 wherein said first portion is provided as a coating on said second portion.
54. The modified release product of claim 73 which is a capsule containing said first and second portions.
55. The modified release product of claim 73 which is approximately equally effective when administered to a patient on an empty or full stomach.
56. The modified release product of claim 73 which has the serum guaifenesin concentration profile of Figure 10.